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| 09/760,595      | 01/16/2001  | Alan R. Pelton       | NDC-15              | 4295             |

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EXAMINER

WILKINS III, HARRY D

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1742

14

DATE MAILED: 04/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/760,595

Applicant(s)

PELTON ET AL.

Examiner

Harry D Wilkins, III

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☒ Claim(s) 1-11 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 January 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

1. The rejections under 35 USC 103 based on the Sakamoto reference have been withdrawn in view of Applicant's amendment of the claims.

#### ***Continued Examination Under 37 CFR 1.114***

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 24 February 2003 has been entered.

#### ***Claim Objections***

3. Claim 1 is objected to because of the following informalities: this claim does not contain a proper connective term between the preamble and the steps of the method (e.g., "comprising", "consisting of"). Appropriate correction is required. Since claim 1, previously a product claim, has been amended to be a method claim, the Examiner will look to the previous method claim for how to treat the claim. Original claim 12 recited a method "...which includes the step of...". Such language has been given to have the same meaning as "comprising", thus, the present claim will be treated as using such language.

4. Claims 2-11 are objected to because of the following informalities: each of these claims recites "The device of claim ..."; however, the parent claim (claim 1) is now a

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method claim; thus, each of these claims should be amended to read "The method of claim ...". Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of making a medical device by polishing and oxidation, does not reasonably provide enablement for a step of electropolishing that *produces* an oxide layer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Applicant expressly discloses (see paragraph spanning pages 7 and 8 of specification) that the polishing (preferably electropolishing) removes any existing surface defects, including any oxide scales. Thus, Applicant's own disclosure teaches against the presently claimed method, such that the claimed electropolishing method actually removes surface oxide layers instead of forming them as claimed. Applicant does teach (see paragraph spanning pages 10 and 11 of specification) that the polishing step *allows* a surface oxide layer to be formed, but such a formation would only occur upon exposure of the workpiece to an oxidizing environment, thus, the polishing step does not form the surface oxide layer.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-4, 6 and 8-11 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Trepanier et al (XP-002200502).

Trepanier et al anticipate the invention as claimed. Trepanier et al teach (see abstract) a method of treating a NiTi medical stent that includes a step of electropolishing. Regarding the limitations that the electropolishing produces an oxide layer on the surface of the stent of up to 10 nm depth, wherein the surface region contains not more than 5% Ni by weight (i.e.-has a titanium oxide surface layer), because Trepanier et al teach the same process step (electropolishing) being applied to the same base material (NiTi stent), the method of Trepanier inherently produces the surface oxide layer with low amounts of Ni as claimed.

Regarding claim 2, because Trepanier et al teach the same process step (electropolishing) being applied to the same base material (NiTi stent), the method of Trepanier inherently produces the surface oxide layer with low amounts of Ni as claimed.

Regarding claim 3, Trepanier et al teach (see abstract) that the method of treating the NiTi stent is electropolishing followed by heat treatment that produces an oxide layer (i.e.-is an oxidation treatment).

Regarding claim 4, Trepanier et al teach (see abstract) that the polishing is performed as electropolishing (i.e.-an electrochemical treatment).

Regarding claim 6, Trepanier et al teach (see abstract) that the stent is a NiTi alloy.

Regarding claim 8, Trepanier et al teach (see abstract) that the stent has superelasticity.

Regarding claims 9 and 10, Trepanier et al teach (see 2<sup>nd</sup> page of abstract) that the NiTi alloy contains 50.8 at% Ni, which is 55.86 wt% Ni.

Regarding claim 11, Trepanier et al teach (see title) that the medical devices are stents.

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Trepanier et al (XP 002200502) in view of Suzuki et al (US 4,612,061).

As described above, Trepanier et al teach the invention substantially as claimed. However, Trepanier et al do not teach that the oxidation step was exposure to superheated steam.

Suzuki et al teaches (see abstract) a method of forming an oxide surface layer on a metal. The method includes exposing the metal a steam atmosphere.

The oxidation heat treatment of Trepanier et al and the steam oxidation step of Suzuki et al are considered functional equivalents. The reason that they are considered equivalent is they both perform the same function, i.e.-they both form an oxide surface layer. See MPEP 2144.06.

Therefore, it would have been obvious to one of ordinary skill in the art to have used the steam exposure method of Suzuki et al for the oxidation heat treatment in the method of Trepanier et al because the two processes are functional equivalents. The substitution of equivalents requires no express motivation. See *In re Fount* 213 USPQ 532 (CCPA 1982).

11. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Trepanier et al (XP 002200502) in view of Mayer et al (US 4,148,699).

As described above, Trepanier et al teach the invention substantially as claimed. However, Trepanier et al do not teach that the oxidation step was performed by a chemical treatment.

Mayer et al teach (see claim 1) a surface treatment method for stainless steel that includes, as step (3), the formation of an oxide coating by treatment of the workpiece in an aqueous nitric acid bath.

The oxidation heat treatment of Trepanier et al and the nitric acid bath step of Suzuki et al are considered functional equivalents. The reason that they are considered equivalent is they both perform the same function, i.e.-they both form an oxide surface layer. See MPEP 2144.06.

Therefore, it would have been obvious to one of ordinary skill in the art to have used the nitric acid bath method (i.e.-chemical treatment) of Mayer et al for the oxidation heat treatment in the method of Trepanier et al because the two processes are functional equivalents. The substitution of equivalents requires no express motivation. See *In re Fount* 213 USPQ 532 (CCPA 1982).

12. Claims 5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trepanier (XP 002200502) in view of Nitowski et al (US 5,277,788).

As described above, Trepanier et al teach the invention substantially as claimed. However, Trepanier et al do not teach that the oxidation step was performed as an electrolytic treatment.

Nitowski et al teach (see abstract) that a substrate is anodized in an aqueous solution (i.e.-acidic, neutral or basic) to produce an oxide surface layer.

The heat treatment oxidation step of Trepanier et al and the anodizing step of Nitowski et al are considered functional equivalents. The reason that they are considered equivalent is they both perform the same function, i.e.-they both form an oxide surface layer. See MPEP 2144.06.

Therefore, it would have been obvious to one of ordinary skill in the art to have used the anodizing method of Nitowski et al for the oxidation heat treatment in the method of Trepanier et al because the two processes are functional equivalents. The substitution of equivalents requires no express motivation. See *In re Fount* 213 USPQ 532 (CCPA 1982).



***Response to Arguments***

13. Applicant's arguments filed 24 February 2003 have been fully considered but they are not persuasive. Applicant has argued that the electropolishing minimizes the nickel-rich phase during the oxidation treatment and that the electropolishing step was not taught by Sakamoto.

In response to Applicant's argument, the assertion that the electropolishing treatment minimizes the formation of nickel oxide in the surface layer is unsupported by facts. While the response mentions that it is "well described in the application", the Examiner is unable to find any reference that connects the electropolishing to the preferential formation of the titanium oxide surface layer. From reading the specification, it seems clear that the selective oxidation of titanium occurs by the different oxidation treatments and does not involve the electropolishing step at all. The Examiner invites Applicant to point to a specific disclosure in the specification where the above assertion is made. In addition, Applicant's disclosure does not support the claimed feature that the electropolishing produces the oxide layer. In fact, the specification teaches (see paragraph spanning pages 7 and 8) that the electropolishing removes any surface oxides from the workpiece. Thus, it is not clear how Applicant's arrived at the presently claimed invention, as the invention as disclosed in the specification requires a polishing step, followed by an oxidation step, where the oxidation step, not the polishing step, forms the oxide surface layer.

**Conclusion**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The excerpt from the Surface Engineering volume of the ASM Handbook describes (in the third column of page 867) electropolishing of nickel alloys.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Harry D Wilkins, III whose telephone number is 703-305-9927. The examiner can normally be reached on M-Th 6:00am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Roy V King can be reached on 703-308-1146. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Harry D Wilkins, III  
Examiner  
Art Unit 1742

hdw  
April 16, 2003

  
ROY KING  
SUPERVISORY PATENT EXAMINER  
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